**DMID Protocol #:**      **Subject ID:**

|  |  |  |
| --- | --- | --- |
| Site Name: | | Site SAE Awareness Date: |
| Initial Report Date: | Follow-up #      Date: | Follow-up #      Date: |

1. **SUBJECT INFORMATION**

|  |  |  |
| --- | --- | --- |
| **Gender:** **M** **F** | **Age:**   **Days** **Weeks** **Months** **Years** | **Weight:**     **lbs** **kg** |
| ***If neonate: Gestational age at birth:***      ***Birth weight:***      ***APGAR scores (1min/5min/10min):***     */*     */* | | |
| ***If SAE occurred in an infant: Subject ID above refers to:*** ***Mother*** ***Infant*** | | |

1. **SAE CATEGORY (CHECK ALL THAT APPLY) (21 CFR 312.32(a))**

|  |  |
| --- | --- |
| **Death**  **Life-threatening (immediate risk of death)**  **Hospitalization/prolongation of existing hospitalization**  **Important medical event** | **Congenital anomaly/birth defect**  **Persistent or significant incapacity or substantial disruption of the ability to conduct normal life functions** |
| ***Other Protocol Requirement:*** | |

1. **SAE INFORMATION (Enter ONE event term per SAE form)**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **SAE Term**  (Single medical concept or Final diagnosis) | **Onset Date**  (DD-MMM-YYYY) | **Severity** | **Relationship to Study Product** | **If Not Related to Study Product, Related to** |
|  |  | Mild  Moderate  Severe  Life-Threatening  Death | Not Related  Related | Study procedure:  Other condition/illness:  Other drug:  Other: |

1. **SAE OUTCOME (CHECK ONLY ONE)**

|  |  |  |
| --- | --- | --- |
| Recovering/resolving |  |  |
| Not recovered/not resolved |  |  |
| Recovered/resolved | Date:       (DD-MMM-YYYY) | |
| Recovered/resolved with sequelae | Date:       (DD-MMM-YYYY) Sequelae: | |
| Unknown | | |
| Fatal (death) | Date:       (DD-MMM-YYYY) | |
|  | Autopsy: Not Done Done (Provide Report) Planned Status Unknown | |
|  | Death Certificate:Provided Requested Not Available Status Unknown | |

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1. **STUDY PRODUCT INFORMATION** *(Attach additional pages if needed)*

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  | **Study Product 1** | **Study Product 2** | **Study Product 3** | **Study Product 4** |
| **Study Product Name** |  |  |  |  |
|  | ***Blinded*** | ***Blinded*** | ***Blinded*** | ***Blinded*** |
| **Dosage, Route of Administration, Administration Schedule** |  |  |  |  |
| **Date Started**  (DD/MMM/YYYY) |  |  |  |  |
| **Date Last Taken Prior to SAE Onset**  (DD/MMM/YYYY) |  |  |  |  |
| **Action Taken With**  **Study Product** | Withdrawn  Dose reduced  Dose increased  Dose not changed  Dose interrupted  Unknown  Not applicable  Comments: | Withdrawn  Dose reduced  Dose increased  Dose not changed  Dose interrupted  Unknown  Not applicable  Comments: | Withdrawn  Dose reduced  Dose increased  Dose not changed  Dose interrupted  Unknown  Not applicable  Comments: | Withdrawn  Dose reduced  Dose increased  Dose not changed  Dose interrupted  Unknown  Not applicable  Comments: |

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1. **LABORATORY RESULTS**

**Please list relevant laboratory results below OR attach copies of the results.**

No relevant laboratory tests **OR** Pending, specify tests:

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Test** | **Test Date**  (DD-MMM-YYYY) | **Result** | **Baseline Date**  (DD-MMM-YYYY) | **Baseline**  **Result** | **Site Normal Range**  (including units) |
|  |  |  |  |  |  |
|  |  |  |  |  |  |
|  |  |  |  |  |  |
|  |  |  |  |  |  |

1. **DIAGNOSTIC TESTS (*e.g.* MRI, CT SCAN, ULTRASOUND)**

**Please list relevant diagnostic test results below OR attach copies of the results.**

No relevant diagnostic tests **OR** Pending, specify tests:

|  |  |  |
| --- | --- | --- |
| **Test** | **Test Date**  (DD-MMM-YYYY) | **Results/Comments** |
|  |  |  |
|  |  |  |
|  |  |  |
|  |  |  |

1. **CONCOMITANT MEDICATIONS**

**Please include both prescription and non-prescription medications/supplements.**

**DO NOT include medications used to treat the SAE.**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Medication** | **Start Date**  **(**DD-MMM-YYYY) | **Stop Date**  (DD-MMM-YYYY) | **Total Daily Dose** | **Indication** | **Suspect?** |
|  |  |  | ­­­­­­­­­­ |  | Yes  No |
|  |  |  | Unknown |  |  |
|  |  |  |  |  | Yes  No |
|  |  |  | Unknown |  |  |
|  |  |  |  |  | Yes  No |
|  |  |  | Unknown |  |  |
|  |  |  |  |  | Yes  No |
|  |  |  | Unknown |  |  |
|  |  |  |  |  | Yes  No |
|  |  |  | Unknown |  |  |

**DMID Protocol #:**      **Subject ID:**

1. **EVENT SUMMARY**

|  |
| --- |
| **Please assure that you have included:**  *Chronological summary of the clinical course of the SAE*  *Associated signs and symptoms*  *Subject’s past medical history, family history, social history and allergies (for newborn and pregnant subjects also include maternal history (obstetric and prenatal))*  *Reactogenicity records, current and past (FOR VACCINES ONLY)*  **Attach additional pages and documents as needed.** |
|  |

1. **REPORTER INFORMATION AND SIGNATURES**

|  |  |  |
| --- | --- | --- |
| Investigator Name: | Investigator Signature:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | Date: |
| Reporter Name: | Reporter Signature:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | Date: |
| Reporter’s phone number: | Reporter’s email address: | |